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EXAMINER

SHAY, DAVID M

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3769

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,462	Applicant(s) KNOPP ET AL.	
	Examiner david shay	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on January 21, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The abstract of the disclosure is objected to because the abstract does not give the gist of the claimed invention. Correction is required. See MPEP § 608.01(b). This objection finds basis in Rule 37 CFR 1.72, as clearly set forth in MPEP § 608.01(b).

Regarding the rejection under 35 U.S.C. 102(b), applicant argues that the added language distinguishes over Bille et al ('340). This apparently because the sensor of Bille et al ('340) is a line sensor. The examiner must respectfully disagree. Firstly, since applicant has provided no definition of the term "X-Y directions" other than "transverse to the beam" (see original claim 10). Therefore, if the X direction and Y direction are defined as any two directions which are not the direction in which the length of the linear diode of Bille et al ('340) extends, the information of the diode will indicate "an X-Y position of the natural tissue structure along the X and Y directions as claimed. Secondly, for the device of Bille et al ('340) to be able to track the grid using the linear diode, there must be some datum associated with the scan line currently being transmitted which identifies the currently transmitted scan line with the corresponding scan line from the previous frame (set of scan lines making up the entire scanned field) and as such this associated datum, used by the comparator, will render with the scan line data itself "the first electrical signal" will indicate the X-Y position of the tracked structure. This will be true whether the tracked structure is the corneal apex or the grid of Bille et al ('340).

It is noted that the terms: "optical path means for receiving the laser beam...and for focusing the beam at a distance in a Z direction as desired toward the tissue treatment site"; "beam steering means connected to the optical path means for controlling the position at which the beam is aimed in the X-Y directions; ""beam focusing means connected to the optical path means for controlling the distance at which the beam is focused"; "tracking means for tracking

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eye movements during the progress of the surgery, including X-Y tracking means for tracking the structure of the eye in X and Y directions and Z tracking means for tracking movements of the eye in the Z direction”; and safety interrupt means for interrupting delivery of the laser beam to the patient when it is determined that the tracking means has lost the structure which is being tracked” the satisfy the three pronged test for a means plus function recitation and with be treated as such herein. See MPEP 2181(I)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5, 7, 9, 11, and 14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bille et al. ('340).

Claim 1 requires inter alia, four elements: a laser; an imaging system; a detector; and a processor. Similarly claim 11 requires inter alia, five elements making a beam of light; forming a real time image; measuring a position generating a second electrical signal and transmitting a stabilized beam. It is further noted that both claims 1 and 11 are comprising-type claims, and as such are open ended, allowing references or combinations disclosing elements other than those specifically recited in the claims to be read thereon.

Concerning claim 1, with regard to the laser, there appears to be no dispute regarding Bille et al. ('340) containing this element, thus it will not be discussed further. Regarding the imaging system, “an imaging system forming an image of a natural tissue structure, the natural tissue structure being proximal to the site” is claimed. In order to properly evaluate the meaning of this phrase, particularly with regard to the language in dispute (i.e. the term “natural tissue structure”, as referred to e.g. in the paragraph bridging pages 4 and 5 of the Remand), the

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meaning of this language must be first determined. As is well understood, an applicant may be his or her own lexicographer but, the only reference to the term “natural tissue structure” per se is in the independent claims, however, paragraph [0044], on page 18 of the originally filed disclosure, discusses “any natural eye feature located in proximity of and structurally contiguous to the target site will serve as the tracking landmark”. The same paragraph also specifically mentions the optic disk, vessel configurations, and the limbus as suitable for the landmark. The term “limbus” is defined as “the edge boarder, or fringe of a part.” (Stedman’s Medical Dictionary, 26th Edition), while the limbus of the cornea is defined as “the margin of the cornea overlapped sclera, corneal margin, sclerocorneal junction.” (Stedman’s Medical Dictionary, 26th Edition). The imaging system of Bille et al. (’340) includes the elements 58, 56, 70, 72a, and 72b, illustrated in Figure 2 of Bille et al. (’340), acts on the light produced by diodes 66 and reflected off of the cornea (a natural tissue structure), along path 68 (see column 5, line 45 to column 6, line 4). The examiner emphasizes here that the image produced by the imaging system described above is from the entire field of view of the system, thus while the image may include at least some of the structures which applicant alleges as artificial and which are produced to form grid 60 of Bille et al. (’340), it must include the intervening unmodified cornea (the “natural tissue structure”), as well as portions of the cornea outlying the “grid” as will be set forth in more detail later. It is noted that while the specification discusses a natural “feature” this particular terminology is judiciously avoided with respect to the claims and arguments directed thereto, both in the Brief on Appeal and the remarks set forth in the response filed September 12, 2005. The ordinary and customary meaning of the term “structure” is “a tissue or formation made up of different but related parts” (Stedman’s Medical Dictionary, 26th Edition). The

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ordinary and customary meaning of the term “feature” is “a prominent or distinctive aspect, quality, or characteristic” (the American Heritage Dictionary, 1982; there is no definition of the term “feature” in Stedman’s Medical Dictionary, 26th Edition). Clearly the term structure is intended to cover a certain tissue broadly {see for example the penultimate sentence in paragraph [0084] on page 27 of the originally filed disclosure, which refers to “the structures behind the cornea (iris, lens, etc.)”}, while the term “feature” relates to e.g. the limbus, which is a distinct characteristic of the structure known as the cornea. Thus the claimed invention to which the reference is applied merely requires that the tissue be imaged, not the “landmark” discussed in paragraph [0044], although the comprising-type claim does encompass embodiments wherein any such landmark may also be imaged as well. Therefore, it is clear that appellant’s broadly cast claims, which merely require that a “structure” rather than the more narrow “feature” be imaged fairly encompass the imaging of e.g. the cornea.

While the examiner feels that this is a full and complete explication of the manner in which clearly shows that the claims at bar read on at least the imaging system aspect of the claims to which it is applied, there are some other aspects of Bille et al. (’340), with respect to the instant claims that bear mention. It is not disputed that Bille et al. (’340) also teach, in addition to tracking the “grid” on the eye, tracking the eye based on a reference provided by either the eye’s symmetry axis (see, the originally filed disclosure, page 10, lines 17-19). However, it is respectfully submitted that Bille et al. (’340) also teach that the tracking can occur whether “the reference alignment is made directly on the visual axis of the eye, or on the visual axis as determined by its relationship with the eye’s axis of symmetry.” (see column 3, lines 4-7). With regard to this admission on the part of applicant the examiner notes that the corneal

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apex is a “natural tissue structure” and as such the use of this structure to stabilize the beam fulfills the claim language as well. The foregoing aside, examiner further respectfully notes that one of ordinary skill in the art is an ocular surgeon, a profession requiring not only 12 years of primary and secondary school, but 4 years of college, 4 more years of medical school, and additional years as an intern before qualifying as an ocular surgeon, thus the level of skill of one of ordinary skill in the art is very high. The determination of the axis of symmetry of the eye in a patient that is unwilling or unable to cooperate is discussed more fully in column 6, lines 23 to column 7, line 21, of Bille et al. ('340). In lines 50-61 in particular, a scanning along lines from the sclera, the iris and the pupil is performed. However, to view the iris, requires the light pass through the clear part of the eye known as the cornea, thus transitioning from the sclera to the cornea necessarily requires traversing the boundary thereof. i.e. the limbus, as set forth above, the limbus is one of the preferred features tracked by the instant device. Further, as a plurality of scans are desired, to provide greater precision (see column 6, lines 62-68), and as the relative position of the eye with respect to the scan line must be known for any meaningful increase in precision to be achieved, one of ordinary skill in the art would readily understand that when performing this procedure on the unrestrained eye the eye must be tracked by matching the intensity variations of the scan line associated with the features such as the sclera, [limbus], iris, and pupil (recall that this procedure is preparatory to determining the offset between the visual axis and the axis of symmetry, more fully explained in column 8, lines 19-43, thus the reflection of the corneal apex cannot be used to determine the relative location of these multiple scan lines on the moving eye). Thus tracking the limbus by the device, at least when determining the offset of the visual and symmetric axes of the eye is taught by Bille et al. ('340).

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The third element of claim 1 is the detector having the image of the structure formed thereon and generating a first electrical signal in response to the image of the structure, the first signal being related to the position of the structure. Examples of appellant's preferred embodiment for such a detector include "linear position sensing detectors" (see originally filed disclosure, page 18, line 10, paragraph [0044]). It is the examiner's view that the "linear diode 76" of Bille et al. ('340), (see column 6, lines 4-10), constitutes such a linear position sensing detector. The fourth element of claim 1 is the processor adapted to generate a second signal stabilizing the beam of treatment light energy. This element reads on the "comparator 28" taught at column 6, lines 11-22: "... linear diode is operatively connected to comparator 28. Through this connection, information concerning the movement of grid 60 can be transmitted to comparator 28 for comparison with the signal representative of the reference alignment. Comparator 28 then generates an error signal proportional to the difference between the actual position of the grid 60 as sensed by the linear diode 76, and the desired position of the grid 60 in its reference alignment. This error signal is used by the fine tuner 24 to guide laser beam 64 in a manner that reduces the error signal to null."

With regard to claim 11, it is the examiner's view that the operation of the laser of Bille et al. ('340) constitutes the "making..." step; collecting the light from diode array 66 with the optical system as set forth above with respect to claim 1 constitutes the "forming..." step; processing the output of the linear diode 76 using the comparator as set forth above constitutes the "measuring..." step; producing the signal the is output to the fine tuner 24 as set forth above constitutes the "generating..." step and the disclosure of the use of the laser for ocular surgery,

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which surgery includes surgery that alters the refraction of the cornea constitutes the “transmitting...” step.

Bille et al. ('340) instructs the artisan of ordinary skill to use the system set forth therein with the system described in Bille et al. ('718).

Claims 1-9 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al ('340) in combination with Bille et al, ('718), Jean et al, Cornsweet et al and the admitted prior art of the use of an analog processor in place of a computer. Bille et al. ('340) teaches an eye tracking laser surgical device which will track the eye in X-, Y-, and Z-directions, including a processor, a detector, a laser, a display, and an imaging system. Bille et al. ('718) teaches a laser redirecting system to keep the surgical laser trained on the eye as the eye moves, including steering means for the X- and Y- directions and a focusing means. Jean et al expressly teach providing a stabilized image of the eye in real time. Cornsweet et al teach the use of a quadrant detector to serve as the image detector. It would have been obvious to the artisan of ordinary skill to employ the laser steering method and device as taught by Bille et al. ('718) in the method and device of Bille et al. ('340), since Bille et al. ('340) specifically say to do so, to employ the stabilized imaging method and device of Jean et al, since this is required in diagnosis and therapy, as taught by Jean et al, and to employ the quadrant detector of Cornsweet et al, since this would also serve as the image detector and would allow a more simplified signal processing arrangement, since there would be no need for the scanner and since Bille et al. ('340) merely disclose the linear diode as a preferred sensor, and to employ an analog processor rather than a computer, since analog processors respond more quickly than digital processors, official notice of which has already been taken, thus producing a device such as claimed.

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Claims 10 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bille et al. ('340) in combination with Bille et al. ('718), Jean et al, Cornsweet et al and the admitted prior art of the use of an analog processor in place of a computer as applied to claims 1 and 11, and further in combination with Kohayakawa. Kohayakawa teaches that when the eye moves, the laser must be stopped and the eye realigned before the surgery is resumed. It would have been obvious to the artisan of ordinary skill to employ the laser shut down technique suggested by Kohayakawa in the combined device and method of Bille et al. ('340) and Bille et al. ('718), and to implement it automatically, since this is merely the provision of automating a manual process, which is obvious, (see *In re Venner*, 262 F.2d 91, 120 USPQ 192 (CCPA 1958)) and since this is required for the surgery to be successful in the case that the eye moves out of range, thus producing a device such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 and 11-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,966,197 in

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combination with Jean et al, and Cornsweet et al and the admitted prior art of the use of an analog processor in place of a computer. The patent claims an X-Y tracking device including a pair of linear detectors. Jean et al expressly teach providing a stabilized image of the eye in real time. Cornsweet et al teach the use of a quadrant detector to serve as the image detector. It would have been obvious to the artisan of ordinary skill to employ the stabilized imaging method and device of Jean et al, since this is required in diagnosis and therapy, as taught by Jean et al, and to employ the quadrant detector of Cornsweet et al, since this would also serve as the image detector and would allow a more simplified signal processing arrangement, since there would be less pixels to process, and to employ an analog processor rather than a computer, since analog processors respond more quickly than digital processors, official notice of which has already been taken, thus producing a device such as claimed.

Claims 10 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 5,966,197 in combination with Jean et al, and Cornsweet et al and the admitted prior art of the use of an analog processor in place of a computer, as applied to claims 1-9 and 11-14 above, and further in combination with Kohayakawa. Kohayakawa teaches that when the eye moves, the laser must be stopped and the eye realigned before the surgery is resumed. It would have been obvious to the artisan of ordinary skill to employ the laser shut down technique suggested by Kohayakawa in the combined device and method applied to claims 1-9 and 11-14, and to implement it automatically, since this is merely the provision of automating a manual process, which is obvious, (see *In re Venner*, 262 F.2d 91, 120 USPQ 192 (CCPA 1958)) and since this is required

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for the surgery to be successful in the case that the eye moves out of range, thus producing a device such as claimed.

Claims 1-9 and 11-14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,283,954 in combination with Jean et al, and Cornsweet et al and the admitted prior art of the use of an analog processor in place of a computer. The patent claims an X-Y tracking device including a pair of linear detectors. Jean et al expressly teach providing a stabilized image of the eye in real time. Cornsweet et al teach the use of a quadrant detector to serve as the image detector. It would have been obvious to the artisan of ordinary skill to employ the stabilized imaging method and device of Jean et al, since this is required in diagnosis and therapy, as taught by Jean et al, and to employ the quadrant detector of Cornsweet et al, since this would also serve as the image detector and would allow a more simplified signal processing arrangement, since there would be less pixels to process, and to employ an analog processor rather than a computer, since analog processors respond more quickly than digital processors, official notice of which has already been taken, thus producing a device such as claimed.

Claims 10 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,283,954 in combination with Jean et al, and Cornsweet et al and the admitted prior art of the use of an analog processor in place of a computer, as applied to claims 1-9 and 11-14 above, and further in combination with Kohayakawa. Kohayakawa teaches that when the eye moves, the laser must be stopped and the eye realigned before the surgery is resumed. It would have been obvious to the artisan of ordinary skill to employ the laser shut down technique suggested by Kohayakawa

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in the combined device and method applied to claims 1-9 and 11-14, and to implement it automatically, since this is merely the provision of automating a manual process, which is obvious, (see *In re Venner*, 262 F.2d 91, 120 USPQ 192 (CCPA 1958)) and since this is required for the surgery to be successful in the case that the eye moves out of range, thus producing a device such as claimed.

Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,702,809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-7, 9-11, 14, and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 6,726,680. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires

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elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-7, 9-11, 14, and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 6,913,603. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 27-34 of copending Application No. 10/124,891. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent application "anticipate" the instant application claims. Accordingly, the instant application claims are not patentably distinct from the patent application claims. Here, the patent application claims

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require elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent application claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments with respect to claims 17, 19-31, and 39-48 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Thursday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ali Imam, can be reached on Monday, Tuesday, Wednesday, and Thursday at (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/
Primary Examiner, Art Unit 3769